REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 1, 13, and 31 are currently being amended. Support for the claim amendments can be found, at least, in the specification, e.g., paragraphs 0015, 0063, 0076, 0088, 0137, and 0138, the claims as filed, and the figures, e.g., figures 7a, 7b, and 8. No new matter has been added.

Claim 32 is currently being added. Support for the new claim can be found, at least, in the specification, e.g., paragraphs 0138, the claims as filed, and the figures, e.g., figure 8. No new matter has been added.

This amendment changes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-26 and 31 are now pending in this application.

Rejections under 35 U.S.C. 102

The Office Action rejected claims 1-4, 9, 11-15, 17-19, and 23 under 35 U.S.C. 102(e) as being anticipated by Shigezawa (US Pat 6,641,556). Applicant respectfully disagrees with this rejection.

The present application, in some examples, is directed to a "system for heating a fluid for delivery into a body of a patient," as recited in claim 1, as now amended. The system includes "three or more thermal sensors, at least one thermal sensor positioned approximate to each end of the tube and at least one thermal sensor positioned in between the ends of the tube." The system

includes "a heating element positioned proximate a surface of the tube to heat fluid within the tube, the heating element being controlled based on temperature data from the three or more thermal sensors to generate two or more determined heat gradients through the fluid within the tube." Independent claim 31, as now amended, includes similar claim limitations.

An advantage of the system as described in claim 1, as now amended, is that "the desired output temperature is achieved for the given fluid with minimum amount of required heat input. The reason for doing so is to maximize high flow rate capability without creating a fluid overheating condition when flow is stopped abruptly." (Present Application: paragraph 00138). Figure 8 of the present application, reproduced below, "illustrates the flow data and controls for this process." (Present Application: paragraph 00138).

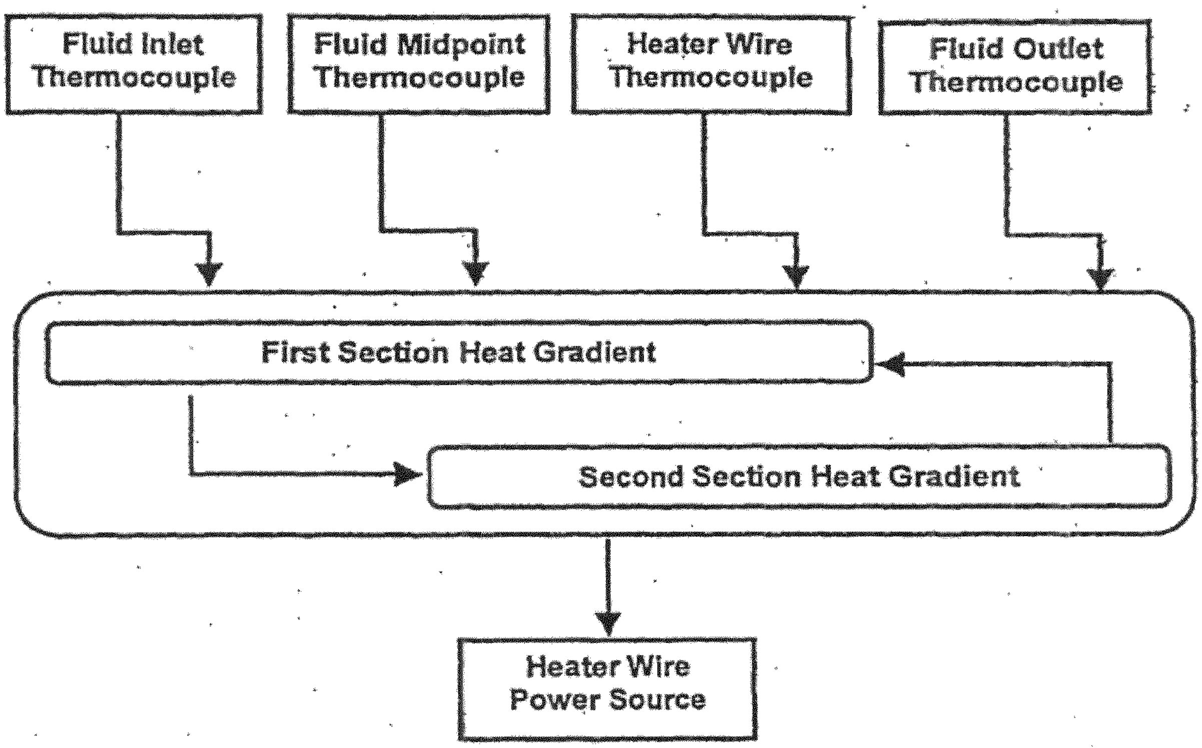

Fig. 8

Present Application

Shigezawa describes an intravenous fluid heating system. (Shigezawa: Abstract). The system in Shigezawa includes "[t]emperature sensors at an entrance and exit of the tubing [that] communicate[s] the temperatures of the unheated and heated fluid, which provides a feedback control circuit for regulating the amount of heat delivered to the fluid." (Shigezawa: Abstract). As illustrated in Figure 1 of Shigezawa, reproduced below, the system in Shigezawa includes "a junction 114, which preferably includes a thermistor or other temperature sensor for detecting the initial temperature of the fluid. The junction 114 is connected electronically to a heat controlling

unit 116 preferably mounted on the IV stand 100 as shown." (Shigezawa: col. 3, lines 16-19). "At or near the cannula 122, a second thermal sensor is provided which measures the temperature of the fluid immediately before the fluid's introduction into the patient, and this temperature is communicated back to the heat controlling unit 116." (Shigezawa: col. 3, lines 28-32). "In a preferred embodiment [of Shigezawa], the proximal end includes a dual thermistor for redundancy wherein a discrepancy between the two sensors forming the dual thermistor triggers an alarm that one of the thermistors has strayed from a predetermined tolerance." (Shigezawa: col. 3, line 64 to col. 4, line 1). The output from the thermistor signals are used "to adjust the power to the heat transformer 188, which in turn adjusts the current in the wires and the heat delivered to the fluid." (Shigezawa: col. 5, lines 1-17).

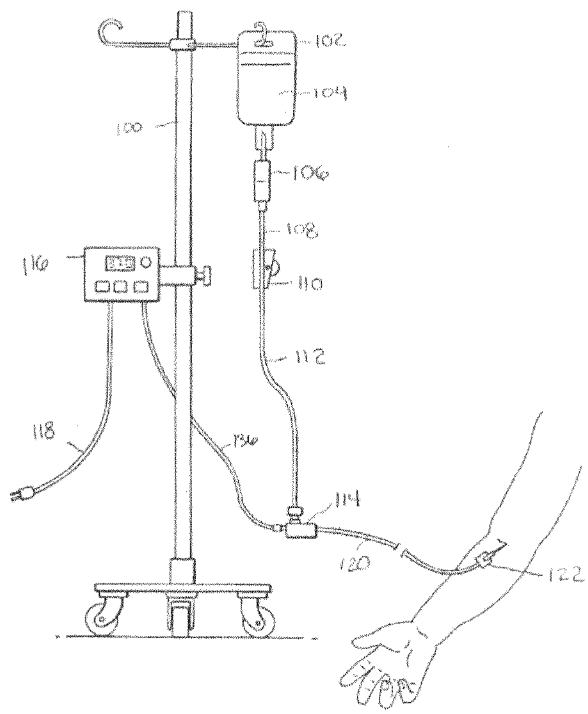

FIG. 1

Shigezawa

Shigezawa does not teach, suggest, or described "three or more thermal sensors, at least one thermal sensor positioned approximate to each end of the tube and at least one thermal sensor positioned in between the ends of the tube" or "the heating element being controlled based on temperature data from the three or more thermal sensors to generate two or more determined heat gradients through the fluid within the tube," as recited in independent claim 1, as now amended, for, at least, the following reasons.

First, Shigezawa does not teach, suggest, or describe "the heating element being controlled based on temperature data from the three or more thermal sensors to generate two or more determined heat gradients through the fluid within the tube." In contrast, Shigezawa describes using the output from the thermistors to control the current in the wire, i.e., a single feedback loop. The system in Shigezawa includes a "heat controlling unit [that] receives temperature signals from the heat sensor unit and adjusts a power current to the junction unit in response to the temperature signals." (Shigezawa: col. 6, lines 14-26). The system in Shigezawa is controlling the power to the heater based on the temperature at the proximal thermistor and the distal thermistor. The system in Shigezawa does not generate two or more determined heat gradients through the fluid based on the temperature data nor could it as the system in Shigezawa only processes an input temperature and an output temperature. Thus, Shigezawa does not teach, suggest, or describe this claim limitation.

Second, Shigezawa does not teach, suggest, or describe "three or more thermal sensors, at least one thermal sensor positioned approximate to each end of the tube and at least one thermal sensor positioned in between the ends of the tube." In contrast, Shigezawa describes two proximal thermistors used for redundancy purposes at the junction 114 and one distal thermistor at the cannula 122. In other words, Shigezawa does not describe a thermal sensor at each end of the tube and a thermal sensor in the middle of the tube. Thus, Shigezawa does not teach, suggest, or describe this claim limitation.

Accordingly, Shigezawa does not describe, teach, or suggest a system that includes the elements of independent claim 1, at least, for the reasons as described above. As such,

independent claim 1 and claims 2-4, 9, 11-15, 17, 10, and 23, which depend from claim 1, directly or indirectly, are now in a condition for allowance based on their distinctions from the cited references. Further, new claim 32 depends from independent claim 1 and is in a condition for allowance based, at least, on its distinctions from the cited references.

Rejections under 35 U.S.C. 103

The Office Action rejected claims 5-8, 22, 24-26 and 31 under 35 U.S.C. 103(a) as being unpatentable over Shigezawa in view of Swenson (US Pat 5,195,976). The Office Action rejected claims 10 and 16 under 35 U.S.C. 103(a) as being unpatentable over Shigezawa in view of Lenker (US Pat 6,746,439). The Office Action rejected claims 20-21 under 35 U.S.C. 103(a) as being unpatentable over Shigezawa in view of Cassidy et al (US Pat 6,175,688). The Applicant respectfully disagrees with these rejections.

Shigezawa is discussed above. Thus, the discussion of Shigezawa is not repeated herein.

Swenson describes an apparatus with an intravenous infusion assembly, a heat exchanger assembly, a controller subassembly, and an energy source subassembly. (Swenson: col. 5, line 66 to col. 6, line 4). The heat exchanger assembly includes heat exchangers, a flow sensor, and an initial and final temperature sensors. (Swenson: col. 6, lines 24-35). After the controller receives a flow signal from the flow sensor, the controller meters electrical power to the heat exchangers based on the temperatures and the IV fluid flow. (Swenson: col. 12, line 66 to col. 13, line 11; col. 13, lines 39-51). As such, Swenson utilizes fluid flow information to determine when to turn the heat exchangers on or off. In contrast, the present application controls the heating element based on temperature data from the three or more thermal sensors to generate two or more determined heat gradients through the fluid within the tube.

Lenker describes an apparatus for controlling the temperature of fluids being administrated to patients and includes a temperature sensor. (Lenker: Abstract; Figure 1). The

apparatus controls the temperature of the fluids by locating the temperature measurement probe at the end of the I.V. tubing nearest the patient and then "overheating the fluid so that it reaches the patient at the desired temperature." (Lenker: col. 2, lines 5-12; col. 3, line 66 to col. 4, line 2; see also Figure 1). Lenker does not describe utilizing three or more thermal sensors, but describes utilizing a single temperature located near the patient as illustrated by the temperature probe 128 in Figure 1 of Lenker.

Furthermore, Lenker does not describe controlling the heating element based on temperature data from the three or more thermal sensors to generate two or more determined heat gradients through the fluid within the tube. Rather, Lenker describes overheating the fluid based on a single temperature sensor close to the patient. On the other hand, as described in the specification of the present application, the present application minimizes the variation in temperature of fluid between the source of the fluid and the patient. (Present Application: paragraph 0055). In contrast, the apparatus as described in Lenker "provides for overheating of the fluid so that it cools down to the desired temperature (usually body temperature) by the time it reaches the patient." (Lenker: Abstract). In contrast, the present application generates two or more determined heat gradients through the fluid within the tube based on the temperature data and therefore prevents such dramatic overheating as described by Lenker.

Cassidy describes a patient wearable intravenous fluid heater with a heat exchanger for heating the fluid via a heating element and temperature sensors for sensing the entering and existing temperatures of the fluid. (Cassidy: Abstract; see also Figure 7). Cassidy further describes a controller for controlling the heating element based upon the temperature of the fluid exiting the heat exchanger. (Cassidy: Abstract; col. 8, lines 29-42; col. 10, lines 18-37; see also Figure 7). In contrast, the present application controls the heating element based on temperature data from the three or more thermal sensors to generate two or more determined heat gradients through the fluid within the tube. Rather, Cassidy describes using the input temperature information for the warning system, controlling the heat exchanger based on the output temperature, and determining a fluid rate based on the input temperature. (Cassidy: col. 8, lines

48-52; col. 10, lines 12-17; col. 14, lines 13-20). Furthermore, Cassidy describes controlling the heat exchanger by determining whether the output temperature is above or below a target temperature and turning the heat exchanger off or on accordingly. (Cassidy: col. 10, lines 18-65; see also Figures 10-11). Thus, Cassidy describes using input temperature to control flow rate and output temperature to independently control the heat exchanger. Nowhere does Cassidy describe or suggest using the input temperature and the output temperature in combination to control the heat exchanger. On the other hand, the present application controls the heating element based on temperature data from the three or more thermal sensors to generate two or more determined heat gradients through the fluid within the tube.

Accordingly, Shigezawa, Lenker, Swenson, and Cassidy, combined or separately, do not teach, suggest, or describe a system that includes the elements of independent claims 1 and 31, as now amended. As such, independent claims 1 and 31 and claims 2-26 and 32, which depend from claim 1, are now in a condition for allowance based on their distinctions from the cited references.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of

papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date August 27, 2009 By ____________________

FOLEY & LARDNER LLP
Customer Number: 48329
Telephone: (617) 342-4080
Facsimile: (617) 342-4001

Christopher E. Everett
Attorney for Applicant
Registration No. 51,659